

**REMARKS**

Claims 1-7 and 11-27 are pending in the application. The Examiner has acknowledged that claims 14 and 16 are allowable if drafted as independent claims. Applicants have amended claims 14 and 16 to independent form and claims 7 and 15 to make grammatical corrections. New claims 17-27 are supported in the application as filed. For example, support for claims 17-19 may be found in the specification at page 4, lines 17-24; support for claim 20 may be found in the specification at page 4, lines 8-10; support for claim 21 may be found in the specification at page 4, lines 2-5; and support for claims 22-27 may be found in the specification at page 7, lines 8-27. No new matter is added by this Amendment.

The Examiner has rejected claims 1-5, 7, and 11-13 under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 5,939,323 (Valentini) in view of U.S. Patent Nos. 3,955,719 (Pheulpin), 4,784,055 (Langen), and 4,758,233 (Phillips). The Examiner has rejected claims 6 and 15 under 35 U.S.C. § 103(a) as allegedly obvious over Valentini in view of U.S. Patent No. 6,187,742 (Wozney) and in further view of Pheulpin, Langen, and Phillips. Applicants traverse.

In prior communications, Applicants have submitted evidence, in the form of a declaration by Dr. Hyun Kim, that the compositions of Valentini cannot be injected through the skin as required by the pending claims. The Examiner has not provided argument or evidence to contradict the statements made by Dr. Kim. Instead, the Examiner cites Pheulpin, Langen, and Phillips “to rebut the argument that pastes are

not injectable.” (4/1/04 Office Action, page 3.) Based on these references, the Examiner concludes that “the opinion of Kim is not probative.”

Applicants respectfully note that the issue here is not whether pastes are injectable. (And Applicants respectfully submit that they have never argued that pastes are not injectable.) The issue is whether Valentini teaches or suggests compositions that can be injected through the skin as required by the pending claims. As noted a number of times in response to earlier office actions, the claimed formulations allow for the treatment and repair of closed fractures without an open reduction procedure. The compositions disclosed in Valentini do not.

The Declaration of Dr. Kim is based on his first hand knowledge of the compositions described in Valentini. Dr. Kim describes the compositions of Valentini as containing concentrations of pore formers that are too high to allow injection through the skin. The documents cited by the Examiner do not address this deficiency in the disclosure of Valentini. None of the documents teach compositions that can be injected through the skin of a patient nor do they suggest how an uninjectable composition can be modified to render it capable of injection through the skin of a patient.

More importantly, none of the documents describe a paste containing pore formers as disclosed by Valentini or provides any indication that such a composition would be injectable. As a result, none of these documents suggest that the Valentini composition containing pore formers could be injected at all, let alone through the skin as required by the claims.

Pheulpin, Langen, and Phillips describe devices for the injection of pastes and liquids. Pheulpin refers to a device designed to inject pastes into dental cavities, not

through the skin. Langen refers to an apparatus designed to evenly distribute a paste throughout a piece of meat. The device is not suitable for therapeutic injections of pharmaceutical formulations through the skin of an injured patient. Phillips refers to a disposable injection apparatus designed to prevent the need for cleaning a chamber after every use. Phillips provides no information regarding the substances to be injected other than that it may be a medicament in the form of a cream or paste. Although it is clear that each of these documents describes an injection device that allows a paste to be injected, none of the documents disclose any physical characteristics or requirements of the substance that may be injected through these devices. Accordingly, there is absolutely no basis to believe that the compositions of Valentini would even be injectable through the apparatuses described by Pheulpin, Langen, or Phillips, let alone through the skin as required by the pending claims. Similarly, the documents provide no reason to doubt the accuracy of the statements made by Dr. Kim in his declaration.

The Examiner further rejects claims 6 and 15 by adding Wozney to the group of references. Wozney describes the use of BMP-7 in pharmaceutical compositions comprising hyaluronic acid—but does not disclose injectable formulations. The Examiner included Wozney in this rejection because Valentini does not teach the use of BMP-7, as is required in claims 6 and 15. However, the addition of Wozney provides no additional support for the obviousness rejection. Wozney does not disclose the injectable compositions of the claimed invention, nor does it suggest how to arrive at those compositions, alone or in combination with any of the other cited documents. Accordingly, the addition of Wozney to Valentini, Pheulpin, Langen, and Phillips does

not render claims 6 and 15 obvious. Applicants respectfully request that the rejection of claims 1-7 and 11-13 under 35 U.S.C. § 103(a) be withdrawn.

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

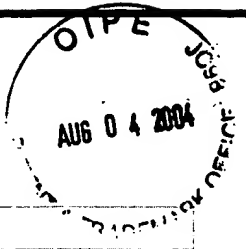
FINNEGAN, HENDERSON, FARABOW,  
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Dated: 8/3/04

By: Elizabeth E. McNamee  
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